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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/586,529 | 05/31/2000 | Colin Collins | 023070-111900US | 6021 |

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EXAMINER

BORIN, MICHAEL L

ART UNIT PAPER NUMBER

1631

DATE MAILED: 01/17/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/586,529

Applicant(s)

Collins et al.

Examiner

Michael Borin

Art Unit

1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 13, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 10-23 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 10-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1631

DETAILED ACTION

Status of Claims

1. Amendment filed 11/13/2002 is acknowledged. Claims 7-9 are canceled. Claim 1 is amended. Claims 1-6,8-23 are pending.
2. Rejection of claims 1-23 under 35 U.S.C. 112, second paragraph, is withdrawn in view of clarification provided by applicant.

Claim Rejections - 35 USC § 112, second paragraph.

3. Claim 1-3,5,6,8-23 are rejected under 35 U.S.C. 112, second paragraph, for failing to particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant. The claims as amended read on genome from an individual with a disease. The term "disease" is vague and unclear. The specification, although providing particular example of cancer, does not define scope of conditions encompassed as "a disease", and one of ordinary skills in the art would not be reasonably appraised of the scope of the invention, especially since defining the term appears essential to distinguish the invention from the prior art. As any condition can be considered a deviation from a reference condition of some

Art Unit: 1631

sort, any condition is considered a "disease" condition in the absence of clear definition of the term.

Claim Rejections - 35 USC § 102 and 103.

4. Rejection of claims 1,3,11 under 35 U.S.C. 102(b) as anticipated by Brosch et al. is maintained for the reasons of record and in view of the following.

In regard to the reference of Brosch et al., applicant argues that the reference fails to teach construction of BAC library from an individual with disease, sequencing of ends of genome inserts in BAC clones, and comparing BAC clones to a second genome. First, the rejected claims 1,3 do not recite BAC clones. In regard to claim 11, the reference does address BAC library; see title and abstract. In regard to "individual with disease", the library in the reference is obtained from tuberculosis bacterium. In regard to comparing to other genomes, the BAC library was "used in a comparative study to reveal polymorphisms" (see abstract). Further, applicant argues that the reference does not teach inserting fragments into vector, sequencing inserted termini. None of these limitation is present in the rejected claims.

5. Rejection of claim 1 under 35 U.S.C. 103(a) as obvious over Brosch et al. in view of Alshtul et al. is maintained for the reasons of record. The primary reference

Art Unit: 1631

which has been discussed above, are used as representative references teaching end sequence profiling of a library of clones. Having obtained such information, one skilled in the art would obviously be motivated to determine whether said sequences have any physiological relevance, i.e., whether they can be identified in any known collection of polynucleotides, or, even better, in a full known genome. There are numerous computational methods of nucleic acid sequence comparison, BLAST method (described in Alshutl et al) being the best known.

6. Claims 1-23 are rejected under 35 U.S.C. 103(a) as obvious over Brosch et al.

First, the claims, as amended, are drawn to test genomes obtained from an individuals with "a disease". As the reference points out that stability and fidelity of the clones in the BAC library represents ideal characteristics for identification of the genomic differences(see p. 2228, second paragraph) it would be *prima facie* obvious for one skilled in the art at the time the invention was made to be motivated to use genome mapping, sequencing and comparative genomics as described in Brosch for various comparative genomics projects including comparing normal vs disease genomes.

Further, if there are any differences between Applicant's claimed methods and that of the prior art, the differences would be appear minor in nature. Although the

Art Unit: 1631

prior art do not teach all specifics of amount and density of clones (as in claims 6,15-18,19-22) or determining their frequency (as in claim 10,13,14), or potential test/reference genome permutations (as in claims 3-5), or executing method using such tools as automated sequencing and computer (as in claims 22,23), it would be conventional and within the skill of the art to determine such parameters and usages as a part of routine optimization which is within the skill in the art to which this invention pertains.

Conclusion.

7. No claims are allowed
8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and

Serial Number: 09/586529

Page 6

Art Unit: 1631

any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

January 14, 2003

mlb

